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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,024	02/09/2005	Katsumi Ihara	2005-0097A	3975

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EXAMINER	
ELLIS, SUEZU Y	

ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
01/11/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/524,024	IHARA ET AL.	
	Examiner	Art Unit	
	Suezu Ellis	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 February 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 February 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/9/05, 5/6/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Priority

If applicant desires to claim the benefit of a prior-filed application under 35 U.S.C. 119(e), a specific reference to the prior-filed application in compliance with 37 CFR 1.78(a) must be included in the first sentence(s) of the specification following the title or in an application data sheet. For benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications.

If the instant application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A benefit claim

filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

If the reference to the prior application was previously submitted within the time period set forth in 37 CFR 1.78(a), but not in the first sentence(s) of the specification or an application data sheet (ADS) as required by 37 CFR 1.78(a) (e.g., if the reference was submitted in an oath or declaration or the application transmittal letter), and the information concerning the benefit claim was recognized by the Office as shown by its inclusion on the first filing receipt, the petition under 37 CFR 1.78(a) and the surcharge under 37 CFR 1.17(t) are not required. Applicant is still required to submit the reference in compliance with 37 CFR 1.78(a) by filing an amendment to the first sentence(s) of the specification or an ADS. See MPEP § 201.11.

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

The information disclosure statements (IDS) submitted on February 9, 2005 and May 6, 2005 are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Drawings

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference characters "1" and "4" have both been used to designate the bottom layer in Fig. 1, while the layer above the bottom layer does not appear to be labeled.

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Regarding claim 1, it is unclear if the adhesive is an adhesive layer, however if so, the adhesive layer must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of

any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The abstract of the disclosure is objected to because the abstract is not a single paragraph and the abstract also does not include complete sentences. Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claim 1, it is unclear if the adhesive recited in lines 3-4 is an adhesive layer or an ingredient that is added into the drug layer. It is also unclear as to what the thickener is added to - is it part of the drug layer or the adhesive layer? Please clarify. Further, it is unclear what applicant means by "in their order" recited in lines 6-7. It is unclear if "in their order" refers to the structural order of the layers or the order of the method steps of making the patch (providing the drug layer, adding adhesive/providing adhesive layer, adding thickener, providing support layer and providing backing layer). Please clarify. The scope of the phraseology is so unclear that "in their order" will not be given patentable weight.

With respect to claim 4, claim language recites "a thickener". It is unclear if the thickener in claim 4 is the same as that in claim 1. If not, the two thickeners need to be better differentiated. However if they are the same, proper antecedent basis is needed (e.g. "the thickener" or "said thickener", etc.). Please clarify.

Claims not specifically addressed are indefinite due to their dependency.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Theeuwes et al. (US 5,298,017).

With respect to claim 1, Theeuwes et al. discloses in Fig. 4, a patch containing fentanyl for mucous membrane of the oral cavity (col. 6, line 49; col. 8, lines 47-51), which can be prepared by laminating on one side of the drug layer which contains fentanyl or its salt as an active ingredient (col. 4, lines 35-38, col. 5, lines 9-17), methyl vinyl ether-maleic anhydride copolymer as an adhesive (col. 12, lines 7, 13-14), and at least one substance selected from the group consisting of hydroxypropyl cellulose, hydroxypropyl methylcellulose and hydroxyethyl cellulose as a thickener (col. 10, lines 8-40, 52-54), a support layer (peripheral insulator) hardly soluble or insoluble in water (col. 12, lines 39-45) and a backing (col. 8, line 9). Examiner notes that claim 1 reads as a product-by-process claim, and that the process limitation (e.g. "prepared by laminating") is not given patentable weight.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1 and 2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamaguchi et al. (US 5,820,877) in view of Inoue et al. (US 4,772,470).

With respect to claims 1 and 2, Yamaguchi et al. discloses in Fig. 1, a permucosal patch containing fentanyl, comprising a drug layer (4) having fentanyl citrate (col. 3, line 60), an adhesive, a thickener (hydroxypropyl cellulose or

hydroxypropylmethyl cellulose) (col. 4, lines 39-41), a support layer (3) that is hardly soluble or insoluble in water (col. 5, lines 2-8), and a backing (2). Yamaguchi discloses laminating on one side of a drug layer (4) (laminating the backing layer) (col. 3, lines 22-32). While the examiner notes that claim language in the preamble that recites "for mucous membrane of the oral cavity" is considered intended use and will not be given patentable weight. Yamaguchi et al. fails to expressly disclose the adhesive being a methyl vinyl ether-maleic anhydride copolymer. Inoue et al. discloses an oral bandage having an adhesive film comprising a methyl vinyl ether-maleic anhydride copolymer (col. 5, lines 33-48; col. 6, lines 6-21). It would have been obvious to one of ordinary skill in the art to modify the material of the adhesive film to be a methyl vinyl ether-maleic anhydride copolymer in order to provide a very thin adhesive film for comfort that has a long-lasting adhesion, as taught by Inoue et al. (col. 5, lines 33-48).

Claims 3 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamaguchi et al. in view of Inoue et al. and further in view of Miller, II et al. (US 2004/0086551).

With respect to claims 3 and 5, the modified Yamaguchi et al. addresses all the limitations of claims 1 and2, however fails to expressly disclose the drug release rate from the drug layer is 50% within one hour. Miller, II et al. teaches a fentanyl patch having a drug release rate of 50% within one hour, as illustrated in Figs. 4 and 5. It would have been obvious to one of ordinary skill in the art to modify the drug release

rate, as desired, in order to provide an effective immediate release of drug from the patch.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yamaguchi et al. in view of Inoue et al. and further in view of Mizota et al. (EP 1 293 199).

With respect to claim 4, the modified Yamaguchi et al. addresses all the limitations of claim 1, however fails to expressly disclose the ratio of the adhesive and thickener is a range selected from 5:95 to 97:3. Mizota et al. teaches a patch having a thickener in a range of 1-50% by mass and an adhesive in the range of 10-60% [0031], [0038], therefore one of ordinary skill in the art could attain the ratio in the range of 5:95 to 97:3. It would have been obvious to one of ordinary skill in the art to modify the ratio of adhesive to thickener of the modified Yamaguchi in order to attain a patch with desired properties. Further, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only routine skill in the art. In re Aller, USPQ 233.

Telephone/Fax Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suezu Ellis whose telephone number is (571) 272-2868. The examiner can normally be reached on 8:30am-5pm (Monday-Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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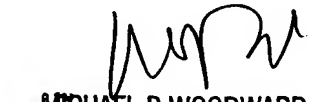

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